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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/530,542

10/27/2005

Claudia Bagutti

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11/29/2007

NOVARTIS

CORPORATE INTELLECTUAL PROPERTY

ONE HEALTH PLAZA 104/3

EAST HANOVER, NJ 07936-1080

EXAMINER

DAVIS, MINH TAM B

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

11/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/530,542

Applicant(s)

BAGUTTI ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-9, 12-13, 31-33, drawn to a cleaved teneurin-1 and the cellular target PML, and a method for detecting teneurin-1 signaling, by detecting the amount of said cleaved teneurin-1 and the cellular target PML.

Groups 2-5, claim(s) 1-9, 12-13, drawn to a method for detecting teneurin-1 signaling, by detecting the amount of the cleaved teneurin-1 and the cellular target Zic, ponsin, myc or p53. A method using each of the cleaved teneurin-1 and the cellular target Zic, ponsin, myc or p53 constitutes a single, distinct invention.

Groups 6-20, claims 1-9, 12-13, drawn to a method for detecting signaling of teneurin-2, teneurin-3, or teneurin-4, by detecting the amount of the cleaved teneurin-2, teneurin-3, or teneurin-4, and the cellular target PML, Zic, ponsin, myc or p53. A method using each of the combined cleaved teneurin-2, teneurin-3, or teneurin-4 and the cellular target PML, Zic, ponsin, myc or p53 constitutes a single, distinct invention.

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Groups 21- 24, claims 10-11, drawn to a method for detecting signaling of teneurin-1, teneurin-2, teneurin-3, or teneurin-4, by detecting activity of a reporter gene. A method using each of teneurin-1, teneurin-2, teneurin-3, or teneurin-4 constitutes as single, distinct invention.

Groups 25-28, claims 14-16, drawn to a method for detecting signaling of teneurin-1, teneurin-2, teneurin-3, or teneurin-4, comprising detecting mRNA expression of PAL nucleic acid. A method of detecting signaling of each of teneurin-1, teneurin-2, teneurin-3, or teneurin-4 constitutes as single, distinct invention.

Groups 29-32, claims 14-15, 17, drawn to a method for detecting signaling of teneurin-1, teneurin-2, teneurin-3, or teneurin-4, comprising detecting mRNA expression of Zic nucleic acid. A method of detecting signaling of each of teneurin-1, teneurin-2, teneurin-3, or teneurin-4 constitutes as single, distinct invention.

Groups 33-36, claims 14-15, 18, drawn to a method for detecting signaling of teneurin-1, teneurin-2, teneurin-3, or teneurin-4, comprising detecting mRNA expression of ponsin nucleic acid. A method of detecting signaling of each of teneurin-1, teneurin-2, teneurin-3, or teneurin-4 constitutes as single, distinct invention.

Groups 37-40, claims 14-16, drawn to a method for detecting signaling of teneurin-1, teneurin-2, teneurin-3, or teneurin-4, comprising detecting protein expression of PAL protein, or its activity. A method of detecting signaling of each of teneurin-1, teneurin-2, teneurin-3, or teneurin-4 constitutes as single, distinct invention.

Groups 41-44, claims 14-15, 17, drawn to a method for detecting signaling of teneurin-1, teneurin-2, teneurin-3, or teneurin-4, comprising detecting protein expression of Zic protein, or

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its activity. A method of detecting signaling of each of teneurin-1, teneurin-2, teneurin-3, or teneurin-4 constitutes as single, distinct invention.

Groups 45-48, claims 14-15, 18, drawn to a method for detecting signaling of teneurin-1, teneurin-2, teneurin-3, or teneurin-4, comprising detecting protein expression of ponsin protein, or its activity. A method of detecting signaling of each of teneurin-1, teneurin-2, teneurin-3, or teneurin-4 constitutes as single, distinct invention.

Groups 49-52, claims 19-20, drawn to a method for detecting cell proliferation, by detecting the amount of cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 and the cellular target PML, Zic, ponsin, myc or p53. A method using each of the combined cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 and the cellular target PML, Zic, ponsin, myc or p53 constitutes a single, distinct invention.

Groups 53-56, claims 19-20, drawn to a method for detecting neuronal differentiation, by detecting the amount of cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 and the cellular target PML, Zic, ponsin, myc or p53. A method using each of the combined cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 and the cellular target PML, Zic, ponsin, myc or p53 constitutes a single, distinct invention.

Groups 57-60, claims 19, 21, drawn to a method for detecting neuropathology or cell pathology, by detecting the amount of cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 and the cellular target PML, Zic, ponsin, myc or p53. A method using each of the combined cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 and the cellular target PML, Zic, ponsin, myc or p53 constitutes a single, distinct invention.

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Groups 61-64, claims 22-23, drawn to a method for screening an agent that modulates signaling of teneurin-1, teneurin-2, teneurin-3, or teneurin-4, by detecting cleavage of said teneurin. A method using each of the teneurins constitute a single, distinct invention.

Groups 65-68, claim 24, drawn to a method for screening an agent that modulates signaling of teneurin-1, teneurin-2, teneurin-3, or teneurin-4, by detecting mRNA expression of a gene regulated by said teneurin. A method that detects mRNA of a gene regulated by each of the teneurins constitute a single, distinct invention.

Groups 69-72, claim 24, drawn to a method for screening an agent that modulates signaling of teneurin-1, teneurin-2, teneurin-3, or teneurin-4, by detecting protein expression of a gene, or the activity of the protein regulated by said teneurin. A method that detects the level or activity of a protein regulated by each of the teneurins constitute a single, distinct invention.

Groups 73-76, claims 25, 29, drawn to the use of an agent that modules signaling of teneurin-1, teneurin-2, teneurin-3, or teneurin-4 for making medicament for treating a neuropathological condition, and a method of treating a neuropathological condition, using said agent . A method using an agent that modulates each of the teneurins constitutes a single, distinct invention.

Groups 77-80, claims 25, 29, drawn to the use of an agent that modules signaling of teneurin-1, teneurin-2, teneurin-3, or teneurin-4 for making medicament for prophylactic treating of a neuropathological condition, and a method of prophylactic treating of a neuropathological condition, using said agent . A method using an agent that modulates each of the teneurins constitutes a single, distinct invention.

Groups 81-84, claims 26, 29, drawn to the use of an agent that modules signaling of teneurin-1, teneurin-2, teneurin-3, or teneurin-4 for making medicament for treating tumorigenesis or cancer, and a method of treating tumorigenesis or cancer, using said agent . A method using an agent that modulates each of the teneurins constitutes a single, distinct invention.

Groups 85-88, claims 26, 29, drawn to the use of an agent that modules signaling of teneurin-1, teneurin-2, teneurin-3, or teneurin-4 for making medicament for prophylactic treating of tumorigenesis or cancer, and a method of prophylactic treating of tumorigenesis or cancer, using said agent . A method using an agent that modulates each of the teneurins constitutes a single, distinct invention.

Groups 89-108. Claims 27, 30, drawn to the use of a cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 associated with cellular target PML, Zic, ponsin, myc or p53 for making medicament for treating of tumorigenesis or cancer, and a method of treating of tumorigenesis or cancer, using said cleaved teneurin and the cellular target. A method using each of the combined cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 and the cellular target PML, Zic, ponsin, myc or p53 constitutes a single, distinct invention.

Groups 109-128. Claims 27, 30, drawn to the use of a cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 associated with cellular target PML, Zic, ponsin, myc or p53 for making medicament for prophylactic treating of tumorigenesis or cancer, and a method of prophylactic treating of tumorigenesis or cancer, using said cleaved teneurin and the cellular target. A method using each of the combined cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 and the cellular target PML, Zic, ponsin, myc or p53 constitutes a single, distinct invention.

Groups 129-148. Claims 28, 30, drawn to the use of a cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 associated with cellular target PML, Zic, ponsin, myc or p53 for making medicament for treating of a neuropathological condition, and a method of treating of a neuropathological condition, using said cleaved teneurin and the cellular target. A method using each of the combined cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 and the cellular target PML, Zic, ponsin, myc or p53 constitutes a single, distinct invention.

Groups 149-168. Claims 28, 30, drawn to the use of a cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 associated with cellular target PML, Zic, ponsin, myc or p53 for making medicament for prophylactic treating of a neuropathological condition, and a method of prophylactic treating of a neuropathological condition, using said cleaved teneurin and the cellular target. A method using each of the combined cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 and the cellular target PML, Zic, ponsin, myc or p53 constitutes a single, distinct invention.

Groups 169-172. Claims 31-32, 34, drawn to a composition comprising a cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 associated with cellular target Zic. A composition comprising each of the combined cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 and Zic constitutes a single, distinct invention.

Groups 173-176. Claims 31-32, 35, drawn to a composition comprising a cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 associated with cellular target ponsin. A composition comprising each of the combined cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 and ponsin constitutes a single, distinct invention.

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Groups 177-180. Claims 31-32, 36, drawn to a composition comprising a cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 associated with cellular target myc. A composition comprising each of the combined cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 and myc constitutes a single, distinct invention.

Groups 181-184. Claims 31-32, 37, drawn to a composition comprising a cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 associated with cellular target p53. A composition comprising each of the combined cleaved teneurin-1, teneurin-2, teneurin-3, or teneurin-4 and p53 constitutes a single, distinct invention.

Groups 185-188. Claim 38, drawn to a kit comprising teneurin-1, teneurin-2, teneurin-3, or teneurin-4 and a protease. A kit comprising each of the teneurins constitutes a single, distinct invention.

In addition, Groups 1-20 are also subjected to the following patentably distinct **species** of the claimed invention:

A tag which is GFP, YFP, hemagglutinin, (histidine)⁷ or a DNA binding domain.

The inventions are distinct, each from the other because of the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of

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said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Group I, claims 1-9, 12-13, 31-33 forms a single general inventive concept.

Groups 2-48, 50-52, 54-56, 58-88, 90-108, 110-128, 130-148, 150-168 do not share the same technical feature of group I, because the methods of groups 2-48, 50-52, 54-56, 58-88, 90-108, 110-128, 130-148, 150-168 do not use the combination comprising the cleaved teneurin-1 and the cellular target PML of group I.

Groups 49, 53, 57, 89, 109, 129, 149 are additional use of the combination comprising the cleaved teneurin-1 and the cellular target PML of group I.

Groups 169-188 do not share the same technical feature of group I, because the composition of groups 169-188 do not share a common structure with the combination comprising the cleaved teneurin-1 and the cellular target PML of group I.

Accordingly, Groups 1-188 are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted, even though the requirement be traversed (37 CFR 1.143).

If any one of groups 1-20 is elected, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits, and a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LARRY HELMS can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS
November 09, 2007

/Larry R. Helms/

Supervisory Patent Examiner